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31 January 1997

## STANDARD OPERATING PROCEDURE D65-09-01

From: D65

To: D65 Division

Subj : DIVISION PROCESS CONTROL

- 1. <u>Purpose</u>. To establish a system and provide instructions for establishing and use of work order and work instructions, production equipment checking and monitoring, qualification and control of special processes, and establishing criteria and responsibility for maintenance of the production environment.
- 2. <u>Scope and Application</u>. This procedure applies to production, installation, and servicing processes directly associated with products and services of the Division.
- 3. <u>Policy</u>. Control of Division processes and equipment and production area maintenance is essential to production and delivery of quality products. All Division personnel are responsible and accountable for ensuring close adherence to this procedure.
- 4. <u>Procedure</u>. This procedure identifies tasking order processes and functions, work instructions, process control and monitoring, control of special processes, maintenance of production equipment, and maintenance of production work areas.
- a. <u>Tasking Orders</u> Tasking orders received from a sponsor/customer will be reviewed by the lead engineer, project engineer, or program manager in each branch and approved by QA before issue.
- (1) <u>Administration and Routing</u> All orders and/or tasking to manufacture, repair, and/or overhaul a product will be sent to the responsible branch using a tasking order. The tasking orders will identify the funding amount and source, specific tasking information and requirements, and all required product information such as nomenclature, type, part number, quantity, and serial numbers of the product. Tasking orders will accompany products through all Division operations up through product delivery. The tasking order will contain the production and quality plans and will list all operations and processes, including inspections and testing, required by the product. It will also reference drawings, specifications, material lists, instructions, acceptance criteria, and other technical documents that are required for production and inspection. Copies of the documents will be enclosed with the tasking order if the referenced documents are not permanently placed in the document stations in production areas.

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Upon completion of an operation or inspection, the operator and/or inspector will date and initial the tasking order on the line where the operation is called out.

- (2) <u>Functions</u> The tasking order has many functions. It specifies the production and quality plans. It provides the work, process, workmanship, and inspection instructions and criteria by referencing appropriate technical documents. It is the means for inspection status identification of products. It is a record of product configuration and traceability, and is a record for in-process and final inspections. After products are completed, the work orders are retained and stored in accordance with SOP D65-16-01, Division Quality Records.
- b. Work Instructions Production\Repair\Overhaul personnel will be instructed in the performance of critical or complex operations identified in written instructions and posted notices. Work instructions will explain how to operate production equipment and machines, define what steps are required to perform certain operations and inspections, and warn against safety hazards. Work instructions will be established for all operations where it is deemed that absence of such instructions would adversely affect quality. When deciding whether work instructions are needed for specific operations, the following will be considered:
  - (1) Importance of the operation and its potential impact on quality
  - (2) Complexity of the operation
  - (3) History of quality problems associated with the operation
  - (4) General level of qualifications and experience of operators
  - (5) In-house training program pertaining to the operation
  - (6) Availability of qualified replacement operators

Results of internal audits and analysis of product nonconformity reports will also be used to determine whether additional and/or more detailed work instructions are required. Work instructions will normally be established by each branch, but must be reviewed and approved by QA before issue. The rules governing issue and control of work instructions are provided in Procedure SOP D65-05-01, Division Quality System Documentation, and in Procedure SOP D65-05-02, Division Document Control.

- c. <u>Process Control and Monitoring</u> Processes will be controlled using one or several of the following process control methods:
  - (1) Written process procedures
  - (2) Operator training and/or certification
  - (3) Process equipment qualification
  - (4) Qualification of process results
  - (5) Continuous process monitoring and statistical analysis

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Each branch will be responsible for selecting appropriate process control methods for their particular processes. The means and methods employed for controlling processes will be documented and the results of process control recorded. The documentation and records can be in the form of process procedures, equipment setting checklists, equipment and process qualification reports, process monitoring charts, statistical analysis reports, operator training records and certificates. Each branch will be responsible for establishing and maintaining appropriate process control documentation and records. Simple processes whose results can be readily verified do not have to be formally controlled, as long as their quality performance history is satisfactory.

- d. <u>Special Process</u> Special processes are those processes whose results cannot be fully verified by subsequent nondestructive inspections. All special processes will be formally controlled. Each branch and QA will be jointly responsible for identifying special processes used in production, repair, and overhaul operations as well as for prescribing procedures, methods, and means for controlling and, if required, recording such processes. Production will establish and maintain appropriate process control documentation and records.
- e. <u>Production Equipment</u> Technical data sheets and maintenance manuals for production machines and equipment will be kept in each branch. Maintenance will be performed in accordance with equipment manufacturer's recommendations and specifications. Each branch will keep records of maintenance and repairs performed. Performance and accuracy of production equipment will be continuously monitored through regular inspection of items processed by the equipment. Operators will be instructed to immediately report any perceived or potential equipment problems to their supervisor.
- f. <u>Production Environment</u> The cleanliness and maintenance of production areas will be emphasized by the management as an important prerequisite for quality. Personnel are encouraged to report substandard conditions such as inadequate ventilation, excessively high or low temperatures, poor lighting, and others that may adversely affect performance and product quality. QA will regularly survey the production areas to identify unauthorized storage of material, products, scrap, tools, supplies, and other such items outside of designated storage areas. QA has the authority to request clearing and cleanup of production and storage areas at any time and can temporarily shut down production areas until corrective action(s) are taken if appropriate.

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